

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
4 November 2004 (04.11.2004)

PCT

(10) International Publication Number
WO 2004/093819 A3

(51) International Patent Classification⁷: A61K 9/20, 9/14

(21) International Application Number:
PCT/US2004/012776

(22) International Filing Date: 21 April 2004 (21.04.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/464,295 21 April 2003 (21.04.2003) US

(71) Applicant (for all designated States except US): EURO-CELIQUE, S.A. [LU/LU]; 122 Boulevard de la Petrusse, L-2330 Luxembourg (LU).

(72) Inventors; and

(75) Inventors/Applicants (for US only): OSHLACK, Benjamin [AU/US]; 351 E. 84th Street, New York, NY 10028 (US). HUANG, Hua-Pin [US/US]; 68 Birch Street, Englewood Cliffs, NJ 07632 (US).

(74) Agents: MARKEY, James, G. et al.; Jones Day, 222 East 41 St. Street, New York, NY 10017-6702 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
3 March 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2004/093819 A3

(54) Title: TAMPER RESISTANT DOSAGE FORM COMPRISING CO-EXTRUDED, ADVERSE AGENT PARTICLES AND PROCESS OF MAKING SAME

(57) Abstract: The present invention relates to co-extruded pharmaceutical compositions and dosage forms comprising an adverse agent, such as an opioid antagonist, which can be sequestered. The pharmaceutical compositions and dosage forms diversion of a dosage form containing an active pharmaceutical agent, such as an opioid. The present invention also relates to methods of treating a patient with such a dosage form, as well as kits containing such a dosage form with instructions for using the dosage form to treat a patient. The present invention further relates to a process for the preparation of such pharmaceutical compositions and dosage forms comprising co-extrusion of a core comprising an adverse agent and a sheath.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/12776

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 9/20, 9/14
US CL : 424/464, 465, 489

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/464, 465, 489

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,228,863 B1 (PALERMO et al) 08 May 2001 (08.05.2001), see entire document.	1-46
A	US 4,582,835 A (LEWIS et al) 15 April 1986 (15.04.1986), see entire document.	1-46
A	US 4,457,933 A (GORDON et al) 03 July 1984 (03.07.1984), see entire document.	1-46

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

10 November 2004 (10.11.2004)

Date of mailing of the international search report

04 JAN 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703)872-9306

Authorized officer

Humera N. Sheikh

Telephone No. (571) 272-0604

Jean Proctor
Paralegal Specialist

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/12776

Continuation of B. FIELDS SEARCHED Item 3:
WEST
particle, drug, opioid antagonist, hydrophobic